REMARKS

Claims 1-74 are pending in the application. Claims 1 and 71 have been amended and claims 42-70 have been withdrawn pursuant to a restriction requirement. No new matter has been introduced by the amendment.

Claim Objections

An objection has been raised to claims 71-74 for use of the abbreviated forms for the recited bacteria. This objection is addressed by the amendment of claim 71 in which the full name of each bacteria has been spelled out in italicized form followed by the abbreviated form in parenthesis.

Rejection Under 35 U.S.C. § 112

Claims 1-41 and 71-74 have been rejected for an alleged failure to provide support for claims reciting particular Magnolia Bark extract concentration in the oral cavity of a user. This rejection is overcome in view of the accompanying Declaration of Minmin Tian together with the following remarks.

The Applicants respectfully assert that one skilled in the art can readily determine the amount of the various ingredients of an edible film that are delivered to the oral cavity of a user from the information provided in the Applicants' specification. In the accompanying Declaration, Dr. Tian has determined the amount of ingredients delivered to the oral cavity per dosage, for both an example of a pullulan-free edible film according to the instant invention, and for an composition example provided by Sherl et. al. (Tian Declaration, paras. 6 and 11). Accordingly, the Applicants respectfully assert that one skilled in the art would not be required to perform undue experimentation in order to realize the claimed subject matter based upon the Applicants' specification. To the contrary, the claimed subject matter is readily determinable, as demonstrated by Dr. Tian in his accompanying Declaration. The Applicants further respectfully assert that the instant Office Action does not present evidence as to why a person skilled in the art would not be able to make and use the invention defined by the claims from the Applicants' disclosure. (MPEP §2163.04). Accordingly, the Applicants assert that the rejection should be withdrawn.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1-41 and 71-74 have been rejected for ambiguity with respect to the identity of the particular component that relates to the recited concentration. This rejection is overcome in view of the amendment of claims 1 and 71 together with the following remarks.

Claims 1 and 71 have been amended to recite that the composition provides a concentration of Magnolia Bark extract having the specified concentration. The Applicants assert that the amendment removes any potential ambiguity regarding the identity of the component to which the specified concentration is directed.

Rejection Under 35 U.S.C. § 103(a)

Claims 1-41 and 71-74 have been rejected over Barkalow et al. in view of Nanba et al. and/or Sherl et al. These claims have also been rejected over Zyck et al. in view of Nanba and/or Sherl et al. These rejections are overcome in view of the accompanying Declaration of Minmin Tian together with the following remarks.

The Applicants respectfully assert that a *prima fascia* case of obviousness has not been established in the instant Office Action. The Applicants assert that one skilled in the art would not be motivated to combine the teachings of a pullulan-free edible film as disclosed by Barkalow et al. with the dentifrices disclosed by Sherl et al. and Nanba et al. This is at least because those skilled in the art would not be motivated to combine Magnolia Bark extract in an amount that would provide the recited low concentration levels with a pullulan-free edible film. As pointed out by Dr. Tian in paragraph 8 of his Declaration, those skilled in the art consider pullulan to be a necessary ingredient in order to obtain germ kill authenticity with low concentration of antimicrobial agent in an edible film. Dr. Tian further points out at paragraph 11 of his Declaration that even in combination with Triclosan, the amount of Magnolia Bark extract in the formulation disclosed by Sherl et al. contains 14 times more Magnolia Bark extract than the Applicants' invention. Dr. Tian further points out that the efficacy achieved by the Applicants' pullulan-free edible film is surprising given the understanding of those skilled in the art regarding the role of pullulan in an edible film.

As demonstrated by the testing described in paragraphs 6 and 7 of Dr. Tian's Declaration, the Applicants' invention has shown germ-kill efficacy with extremely low concentrations of Magnolia Bark extract in a pullulan-free edible film. In particular, as described in paragraph 6 of Dr. Tian's Declaration, a dosage in the amount of .21 milligrams was found to reduce total bacteria counts in a clinical trial by 49 percent 20 minutes after consumption and 34 percent at 40 minutes after consumption. In paragraph 9 of his Declaration reproduced below, Dr. Tian concludes that these results are unexpected.

> In view of the general understanding of the action of pullulan in edible films, I find it surprising that, in the invention of the '671 application, a pullulan-free combination of sodium alginate, maltodextrin, carrageenan, micro-crystalline cellulose, and a low amount of MBE, provide effective germ-kill against bacteria that cause bad breath. In the invention described in the '671 application, the amount of MBE delivered to oral cavity is below 1 microgram. This amount of antimicrobial agent is much less than would be expected necessary in a pullulan-free edible film that was effective at killing germs causing bad breath. (Declaration of Minmin Tian, para. 9).

Accordingly, the Applicants assert that they have provided evidence of unexpected results with their pullulan-free edible film composition.

The Applicants assert that a *prima fascia* case of obviousness requires that there must be a reasonable expectation of success. (MPEP §2142). The Applicants have presented evidence that the combined teachings of the cited references do not establish a reasonable expectation of success. Further the Applicants assert that obviousness must be considered in view of all of the facts established by rebuttal evidence, and this evidence must be evaluated in consideration of the obviousness rejection. Moreover, the teaching or suggestion to combine the references and the reasonable expectation of success must be found in the prior art and not in the Applicants' disclosure. (MPEP §2143).

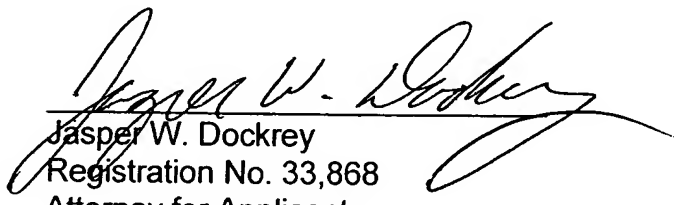
The Applicants assert that one skilled in the art would not be motivated to combine the teachings of the edible film as disclosed by Zyck et al. with the dentifrices disclosed by Sherl et al. and Nanba et al. This is at least because those skilled in the art would not be motivated to combine Magnolia Bark extract in an amount that would

provide the recited low concentration levels with the edible film disclosed by Zyck et al. The Applicants' foregoing remarks pertaining to Barkalow et al. are incorporated herein. The Applicants further assert that Zyck et al. qualifies as a prior art reference under 25 U.S.C. §102(e). As indicated on the face of Zyck et al., this reference and the instant application belong to the same assignee, Wm. Wrigley Jr. Company. The Applicants assert that Zyck et al. should be removed under 35 U.S.C. § 103(c), because the subject matter of Zyck et al. and the claimed invention were, at the time the invention was made, owned by the same person.

Through their submission of Declarations by Dr. Tian and Dr. Dodds, the Applicants have established substantial evidence of non-obviousness. The Applicants assert that this evidence clearly establishes that a combination of the cited references does not render the Applicants obvious. The Applicants are first to develop a pullulan-free edible film having the recited concentration levels. Further, the Applicants have established the efficacy of their claimed composition despite the belief of those skilled in the art that pullulan was a necessary component to achieve an effective edible film having a very low concentration of antimicrobial agent.

The Applicants have made a novel and non-obvious contribution to the art of edible film composition. The claims as issue distinguish over the cited references and are in condition for allowance. Accordingly, such allowance is now earnestly requested.

Respectfully submitted,



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on September 18, 2006
Date of Deposit

Jasper W. Dockrey, Reg. No. 33,868
Name of applicant, assignee or
Registered Representative

Signature
September 18, 2006
Date of Signature

Case No. 1391/1555
Wrigley No. MAGBAR 01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MAXWELL et al.

Serial No.: 10/606,671

Filing Date: June 25, 2003

For: BREATH FRESHENING AND ORAL CLEANSING PRODUCT WITH MAGNOLIA BARK EXTRACT

Examiner:
Ruth A. Davis

Group Art Unit No.:
1761

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Declarant, Minmin Tian hereby declares as follows:

1. I am presently employed as a Senior Technology Scientist by Wm. Wrigley, Jr. Company at the Wrigley Global Innovation Center in Chicago, IL. I hold a PhD. degree in Chemistry from the University of Texas at Austin, Texas, which was awarded in December, 1994. Following graduating from the University of Texas, I was a Post Doctorial Fellow at the University of California-Berkely until June, 1996. Since then, I have worked as a research scientist at three major U.S. oral care product companies. I have held my current position at Wm. Wrigley, Jr. Company since December, 2003.

2. In my capacity as a technology scientist at Wm. Wrigley, Jr. Company, I have investigated a variety of botanic extracts for germ-kill, oral care, and breath freshening applications. I have investigated ingredients that help to maintain tooth plaque pH above 5.7, the critical pH that causes tooth demineralization. I have also studied various natural and synthetic compounds that are active against oral bacteria through a variety of in vitro microbiological testing methods as well as in vivo clinical trials. Furthermore, I have worked with confectionery formulations including breath films, compressed mints, hard and soft candies, and chewing gums. I have recently led a project directed to discovering, identifying, and developing magnolia bark extract for germ-kill, breath freshening, and oral care applications.

3. I have reviewed U.S. Patent Application No. 10/606,671, titled "BREATH FRESHENING AND ORAL CLEANSING PRODUCT WITH MAGNOLIA BARK EXTRACT." I have also reviewed the Office Action of April 24, 2006 and the prior art references cited in the Office Action. In particular, I have reviewed PCT application publication No. WO 02/43657 to Barlalow et al., PCT application publication No. WO 01/85116 to Sherl et al., Japanese application publication No. JP357085319 to Nanba et al. (English abstract only), and U.S. Pat. No. 6,740,332 to Zyck et al. In addition, I have reviewed the patent claims presented in the response that accompanies this Declaration.

4. I consider myself to be a person skilled in the art in the subject matter disclosed and claimed in U.S. Patent Application No. 10/606,671 ("the '671 application"). I have been asked to give opinions on the matters recited in this Declaration and I believe that I am qualified by education and experience to do so.

5. The edible film according to the invention described in the '671 application delivers a very low total amount of magnolia bark extract ("MBE") per unit dose compared to mouthwashes or dentifrices described in the prior art. Specifically, the '671 application describes MBE levels as low as 0.005% by weight. (See for example, para. 0032). Despite these low levels of MBE, the edible films of the invention surprisingly provide antimicrobial efficacy in the oral cavity.

6. I base my opinion, in part, upon testing of edible films prepared according to the '671 application. A pullulan-free edible film was prepared in accordance with the edible film formulations described in the '671 application by others at the Wrigley Global Innovation Center. Table 1 below shows the ingredients and the ingredient concentrations for the edible film. The edible film, which weighed about 46 mg a piece, contained 0.21mg of MBE or 0.45 wt.% MBE.

Table 1. Example of a pullulan-free edible film according to the invention

Compound	Dry conc. %	Amount delivered per dosage (mg)
Na-alginate	30.13	13.86
Maltodextrin	28.24	12.99
Carrageenan corn dextrin	10.15	4.67
Peppermint flavor	8.53	3.92
Microcrystalline cellulose	8.35	3.84
Glycerin	7.56	3.48
Menthol	3.59	1.65
Lectin	1.31	0.60
Intense sweetener	1.16	0.53
Magnolia Bark Extract	**0.45**	**0.21**
Colorant	0.36	0.17
Citric acid	0.17	0.08
Total	100.00	46.00

I am aware that the pullulan-free edible film described above was evaluated for germ-kill effect by a clinical trial. The clinical trial involved 236 subjects. In the clinical trial, the edible film demonstrated surprisingly strong germ-kill effect up to 20 minutes and 40 minutes after consumption. One dosage was found to reduce total bacteria counts by 49% at 20 minutes and 34% at 40 minutes.

7. As shown in Table 1 above, the amount of MBE delivered per dosage of the edible film was 0.21mg of MBE or 4500 ppm. The total germ kill effect with this low dosage of antimicrobial agent is surprising because a 34% to 49% reduction in total bacterial count would only be expected in edible films containing pullulan.

8. Based on existing patents and other literature sources, it is widely believed that pullulan is a polymeric material that operates to enhance the efficacy of antimicrobial agents. For example, the effect of pullulan is explained in the excerpt of U.S. Pat. No. 6,923,981 reproduced below.

> "A further aspect of this invention is that while the amounts of LISTERINE® essential oils are relatively high for incorporation in a film, the film according to the present invention still delivers a lower total amount of essential oils per unit dose when compared to that of LISTERINE® mouthwash. Yet the film suprisingly provides antimicrobial efficacy in the oral cavity. The inventors theorize that the preferred film forming ingredient, pullulan, forms a thin layer on the oral surfaces entrapping the small amount of essential oils which are capable of penetrating into the pits and fissures of the oral cavity to provide sustained antimicrobial efficacy." (U.S. Pat. No. 6,923,981, Col. 4, ll. 4-14)

As stated in the excerpt above, pullulan is thought to be a film forming material that binds to oral surfaces and entraps small amount of germ-kill actives capable of penetrating into the pits and fissures of the oral cavity to provide sustained antimicrobial efficacy. Accordingly, it was believed to be necessary to include pullulan in an edible film in order to obtain germ kill efficacy with a relatively low concentration of antimicrobial agent in the edible film.

9. In view of the general understanding of the action of pullulan in edible films, I find it surprising that, in the invention of the '671 application, a pullulan-free combination of sodium alginate, maltodextrin, carrageenan, micro-crystalline cellulose, and a low level of MBE, provide effective germ-kill against bacteria that cause bad breath. In the invention described in the '671 application, the amount of MBE delivered to oral cavity is below 1 microgram. This amount of antimicrobial agent is much less than would be expected necessary in a pullulan-free edible film that was effective at killing germs causing bad breath.

10. Despite the role of pullulan described in the prior art, based on the results of my testing, I conclude that sodium alginate, maltodextrin, carrageenan, micro-crystalline cellulose and other ingredients in combination with MBE in the particular proportions of the invention provide an effective film forming polymer that binds to oral surfaces and entraps a small amount of MBE. This combination provides a sustained anti-microbial effect even with exceedingly small amounts of MBE.

11. In contrast to the invention described in the '671 application, the Sherl et al. reference describes dentifrice compositions that contain a combination of Triclosan and the phenolic compounds magnolol and honokiol from Magnolia Extract. In

Example II of Sherl et al., an oral care composition is described containing 0.3% MBE and 0.3% triclosan. (Sherl et al., Table II, composition B, pg. 11). As shown in Table 2 below, I have calculated the total amount of MBE delivered to oral cavity by the composition of Example IIB to be about 3mg (based on an average dentifrice dosage of 1g).

Table 2. Example II B of Scherl et al.

Compound	**conc. %**	**Amount delivered per dosage (mg)**
D.I. Water	15.807	158.07
Glycerin	20	200
Carboxymethyl cellulose	1.10	11
Carrageenan	0.4	4.0
Sodium Saccharine	0.3	3.0
Sodium floride	0.243	2.43
Titanium dioxide	0.5	5
Noncrystallizing sorbitol	20.85	208.5
Gantrez S-97	15	150
Silican abrasive	20	200
Silicon thickener	1.5	15
Flavor	1.0	10
Sodium hydroxide 50%	1.2	12
Magnolia Bark Extract	**0.30**	**3.0**
Triclosan	**0.30**	**3.0**
SLS	1.5	15
Total	100.00	1000

The amount of MBE in the composition of Sherl et al. shown above is 14 times higher than that of the edible film composition prepared in accordance with the invention of the '671 application and as set forth above in paragraph 6.

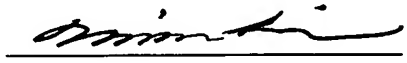
12. Although the Sherl et al. reference describes MBE concentrations ranging from 0.001-50% in an oral care dentifrice, I believe that such dentifrices cannot achieve germ-kill efficacy at a level of MBE below 1 mg per dosage without the presence of Triclosan.

13. Given the description in the prior art of the function of pullulan in edible films and the MBE concentrations necessary for effective germ kill in dentifrices, the results of the pullulan free edible film described in the '671 application is surprising. Accordingly, I do not believe that the invention described and claimed in the '671 application is obvious in view of the a dentifrice containing MBE as taught by Sherl et al. or Nanba et al. and the pullulan-free edible film described by Barlalow et al. or the edible films described by Zyck et al.

14. It is my further opinion that one skilled in the art would be aware of the amount of MBE delivered to the oral cavity based on the description of the invention provided in the '671 application. As shown above, I calculated the amounts delivered per dosage for both the pullulan-free edible film described in the '671 application and the composition described by Sherl et al. One skilled in the art, upon reading the '671 application would be able to readily determine the amounts of MBE delivered to the oral cavity of a user as I have done above.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

September 12, 2006
Date



Minmin Tian